Rejection Under 35 USC 112 first Paragraph

Claims 11-40 were rejected under 35 USC 112, First Paragraph for not enabling "any person skilled in the art ... to practice the invention commensurate in scope with these claims. (See Office Action, Pages 2-3). Applicants respectfully disagree . Examiner admitted on page 2 of the Office Action that the specification is "enabling for treating inflammation." Thus, if the application is enabling for the treatment of inflammation by topically applying a composition comprising an extract of feverfew to a human wherein said extract is substantially free of α-unsaturated γ-lactone, then the specification must also be enabling for the "method of administering an extract of feverfew to a human, said method comprising topically applying a composition comprising an extract of feverfew to said human wherein said extract is substantially free of α-unsaturated γ-lactone" as recited in claim 11 is method step is the same.

Examiner stated that "the specification does not reasonably provide enablement for treating any other disorder that can be treated topically." Examiner cited *In re Wands* to assert that undue experimentation would be required to practice the invention as claimed. Examiner contended that "the potential for successfully treating conditions and disorders is unpredictable especially when there is no disclosure of effective dosage to use for treating disorders." Applicants, however, respectfully disagree. Unlike *In re Wands*, in which the concern of unpredictability for production of antibodies was well supported in the biotechnology arena, this invention involves topically applied plant extract. Plants extracts have been used to treat skin conditions in a wide range of dosages for thousands of years by various cultures and traditions. The substantially parthenolide-free feverfew extract adds additional assurance for its safe and effective topical use, as demonstrated in this invention. Applicants, therefore, contend that the rejection based on unpredictability of the art is erroneous.

As further evidence that the topical application of feverfew extract has utility in addition to the treatment of inflammation, Applicants submit herewith a declaration under 37 CFR 1.132 by Dr. Neena Tierney. As recited in this declaration, Dr. Tierney found that topically applying a composition comprising an extract of feverfew to said human wherein said extract is substantially free of α-unsaturated γ-lactone resulted in a number of benefits such as improved tone and texture of the skin, lightning of the skin, increased evenness of pigmentation, increased skin renewal, and increased collagen crosslinking. Thus, the topical

application of a composition comprising an extract of feverfew wherein said extract is substantially free of α-unsaturated γ-lactone does treat other disorders, such a uneven tone and texture.

In addition, as stated in the prior response filed April 18, 2005, Examiner has not specifically pointed out any applicable law that requires Applicants to recite specific benefits in a method claim.

Accordingly, Applicants respectfully request that the above rejection under 35 USC 112 be withdrawn.

Double Patenting

Claims 1 and 11-40 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of US Patent No. 6,410,062. See page 5 of the Office Action. Applicants agree to submit an appropriate terminal disclaimer upon the indication of allowable subject matter in the present application.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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